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| 10/594,171 | 07/18/2007 | **Tatiana Pavlovna Kljushnik** | TSET3.001APC | 7746 |

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

| EXAMINER | |
|---|---|
| KADAMBI, GEETA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 10/02/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/594,171 | KLJUSHNIK ET AL. | |
| | Examiner | Art Unit | |
| | GEETA KADAMBI | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3 and 5-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 3 and 5 -11 are pending.

### *Election/Restrictions*

1. Applicant's election of Group II in the reply filed on 3/11/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1, 2 and 4 were cancelled. Claims 3, 5-11 are under examination.

The restriction election is made final.

### *Specification*

2. The use of the trademark OXYGENT, AQUAFTEN and GERMABEN II etc., has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. It has been capitalized; however it is not accompanied by generic terminology or ™ or ®.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 9 recites the limitation "wherein said abnormal nervous and/or endocrine regulation" in line 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 10 recites the limitation "wherein said abnormal nervouiangiopathy" in line 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

6. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “nervouiangiopathy” in claim 10 is used. Examiner searched the specification for the applicant’s definition of the term and was unable to find in the most recently submitted specification dated 6/12/08. Examiner further searched in Google and PUBMED for art accepted definition of the word “nervouiangiopathy” and did not get any results. The Google and PUBMED search page is attached as evidence. The term is unclear because the specification does not clearly define the term nor it is art accepted terminology.

***Claim Objections***

7. Claims 7, 8 and 9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim 3 from which it depends. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 7, 8 and 9 are interpreted by the examiner as functional limitation which are characterization of the application rather than further limiting claim 3. Therefore they fail to further limit claim 3.

***Response to Applicants arguments***

8. Claims 3, 5, 6, 7, 8, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kayakiri et al. (US Patent 6348474) in view of Brunetta et al. (US Patent 5562911) (claim set dated 1/23/08)

The applicant argues the rejection based on Kayakiri et al. that it does not teach "increasing blood flow" in para 3 of their response dated 6/12/08. However the applicant is directed to their claim set dated 1/23/08 (upon which the rejection mailed on 3/12/08 was based) does not claim increase in blood flow in any claims. The claim language of claim 3 is reproduced for the benefit of the applicant to corroborate that the claim only stated "regulation of a skin capillary blood flow":

3. (Currently amended) A method for treating abnormal of abolition of distortions ~~of neurogenous~~ nervous and/or endocrine **regulation** ~~of a system of~~ a skin capillary blood flow comprising applying a perfluorocompound perfluorocompounds emulsion to a cutaneous surface

Diabetes and other disorders listed in Kayakiri et al. (cited by applicant in the response) are endocrine disorders and have perturbation on the skin for example diabetes dermatopathy. Applicants admit that "positive effect of the perfluorocompounds and other preparations to the skin **may be connected with properties apart from an effect on skin capillary blood flow**", which clearly does exclude that perfluorocompounds do have effect on skin capillary blood flow. The properties of the compounds are carried with it no matter what is being claimed as intended use, so perfluorocompound would inherently increase the blood flow along with other functions.

If perfluorocompounds are used for wound healing purpose as quoted by the applicant (pg 6, para 2) it would increase blood flow as it is known in the art that one of the steps in wound healing is angiogenesis which leads to increased blood flow. Brunetta et al. clearly teach dermatological application of perfluorocompounds with antioxidant, which reads on the claim 5 of the claim set. In view of above arguments and the previous office action the rejection is maintained. Applicant's arguments are taken into consideration and were not found persuasive. It is observed by the examiner that the applicants have amended their claims and submitted new set of claims on 6/12/08 in response to the office action mailed on 3/12/08.

The applicants have amended their claims to overcome the previous rejections, hence new grounds of rejections are as follows.

***Claim Rejections - 35 USC § 103***

***(New grounds of rejection)***

9. The text of those sections of Title 35 US code is not included in this section and can be found in a prior office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 3, 5-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penske et al. (US 5851544) and Kligman AM (US 4603146).**

'544 teaches an inventive composition containing fluorocarbons can have straight chains such as perfluorooctane or perfluorodecane or may contain some ring structures such as perfluorodecalin or (col 2, ln 66-67, col 3, ln 1). '544 also teaches a method to improve blood flow and circulation to skin, consequently , improve blood supply of endogenous oxygen to skin. The increased blood flow may in turn result in reduced appearance of wrinkles and aged or photo aged skin, reduced signs of cellulite, improved skin color, improved condition of hair roots, improvements of skin radiance and clarity and finish, and an overall healthy and youthful appearance of the skin (col 2, ln 27-34).

'544 teaches the addition of water, liquid or solid emollients, solvents, humectants, thickeners and powders (col 3, ln 41-43). '544 teaches that the preferred composition is a cosmetic composition for treating skin aiming to achieve anti-aging benefits. Such compositions preferably include sunscreen, to further minimize aging, wrinkling and photo damage to skin which result from exposure of skin to harmful UV-A and UV-B rays (col 3, ln 60-65) and they are topical application cosmetic products to human skin, especially for increasing the supply of endogenous oxygen and thus preventing or reducing the above mentioned damages (col 6, ln 47-52). '544 in table 2 teaches the use of the composition as an emulsion containing perfluorocompound

perfluorodecalin in line 15. '544 in example 2 describe how they measure and asses the benefit of the application of the emulsion. '544 describes an erythema meter (Diastron) being used to measure spectrophotometrically the level of pinkness on the surface of human skin as an indicator of the level of blood flow. Increased blood flow to the skin typically results in increased pinkness (col 8, ln 52-56). '544 shows data in Table 2 that pinkness of the skin was significantly greater after treatment with various levels of fluorocarbon emulsions infused with carbon dioxide as compared to fluorocarbon controls. This demonstrates that blood flow to the skin was higher after treatment with fluorocarbons containing carbon dioxide (col 9, ln 21-26). This renders the instant claims 3 and 11 obvious because the symptoms of aging such as wrinkles would enable a person of ordinary skill in the art to identify that the person is in need of a treatment to reduce the wrinkles and treat them by applying an emulsion comprising of fluorocarbon with other additives to increase the blood circulation to the skin (instant claims 3 and 11).

'544 further teaches the use of coloring agent, perfumes, dyes, antibacterial agent and antidandruff agent to be included in the composition (col 6, ln 40-44). This renders the instant claim 5 obvious as antibacterial would be the other biologically active compound along with other ingredients that are listed in instant claim 5.

'544 does not teach increase synthesis of collagenous and elastin fibers in capillary wall, reserve capillary blood flow increase or increased flexibility of walls of precapillary arterioles.

'146 teaches in their abstract that various effects of aging of skin due to impairment of differentiation of epidermal epithelial cells and loss of collagen fibers, abnormal changes in elastic fibers and deterioration of small blood vessels in the dermis of the skin are retarded by applying topically to the epidermis in a maintenance therapy program effective amounts of vitamin A acid (tretinoin) such that epithelial growths are substantially reduced and prevented and the skin substantially regains and maintains its firmness, turgor and elasticity. Moreover, with persistent treatment dermal blood cells and vessels increase and the epidermis and dermis thicken, resulting in improved ability of the skin to sense, resist and recover from irritation or injury. Further, hyper pigmentation, lines and wrinkles due to aging are reduced and prevented. The treatment is particularly useful for human facial skin and preferably applied in amounts insufficient to cause excessive irritation. Vitamin A acid used in this cited prior art would be equivalent to the "medicinal compound" or "another biological active compound" of instant claim 5. '146 teaches that first a prophylactic effect in preventing progression and worsening of the damage with the passage of time. Secondly, various abnormalities are corrected and modified to the extent that the structure and function of the skin acquires the characteristics of younger skin (col 2, ln 34-39). '146 also teaches that effects of the aging of the human skin are the result of underlying structural changes which build up over a period of years and can be associated with loss of sensory acuity and ability to heal wounds, decreased blood flow and decrease in the thickness of the skin. The underlying causes of the above gross skin effects are due to specific changes in the epidermis and dermis as aging

progresses. In the dermis the cells which make the fibers of the dermis become smaller and sparser with increasing age, usually in sun damaged facial skin. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Since the fibrous components comprise more than 90% of the bulk of skin of which 95% is collagen, the degradation of these fibers, especially collagen, is mainly responsible for wrinkling, laxness and loss of elasticity. Small blood vessels become thin walled, dilated and often ruptured. Vascular supply thereby becomes compromised (col 3, ln 50-64). Vitamin A acid treatment increases proliferative activity of epidermal cells (ref) and promotes the formation of a more normal dermis by the production of new collagen layer which not only repairs damaged skin but results in the effacement and prevention of fine wrinkles and lines (col 3, ln 68, col 4, ln 43-46). This renders instant claim 7 obvious as it increases the collagen synthesis.

'146 teaches that Tretinoin (Vitamin A acid) stimulates blood flow and promotes the formation of new vessels. Blood flow is greatly reduced in aged and sun damaged skin. A brisker blood supply improves the physiologic competence of the skin and imparts a livelier, glowing appearance (col 4, ln 48-53). '146 teaches the composition to be an emulsion (col 5, ln 33). The surface temperature of the skin in older people is somewhat lower than the skin temperature in younger people, so that they often feel cold. This is due to a decrease in the blood supply to the skin due to loss of small blood vessels and decreased proliferation of new capillaries and small blood vessels in the skin. This is at least one of the causes of the loss of sensory acuity and response

to pain. Furthermore, the decreased blood supply decreases the rate at which irritants and toxins are cleared from the skin tissue (col 3, ln 3-12). Fibroblasts synthesize the fibers of the dermis; new collagen is laid down, strengthening the physical foundation of the skin. Fibroblasts also make the ground substance which exists between the fibers, allowing these to glide past each other (col 4, ln 31-35). The production of a new collagen layer not only repairs damaged skin but results in the effacement and prevention of fine wrinkles and lines (col 4, ln 44-46). Still further, treatment with vitamin A acid according to the present invention raises the surface temperature of the skin by about 0.5 $^{0}$C due to the greater basodermal flow of blood (col 5, ln 1-5). This renders the instant claim 8 obvious as it would also increase index of reserve capillary blood flow.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the ‘544 and ‘146 because both teach a topical application of emulsion containing perfluorocompound and a biologically active ingredient such as Vitamin A acid on the skin to increase capillary blood flow. Instant claim 3 contains "comprising" language, which would allow a person skilled in the art to add more than perfluorocompound to the method of treatment and instant claim 5 has "another biologically active compound", which is taught by ‘146 as Vitamin A acid that increases skin capillary blood flow when applied as an emulsion topically on the skin. It would be obvious to combine the said references to benefit from treating an aging skin because ‘544 teaches the use of perfluorocompound for increasing the blood flow in the aging skin and other additives such as Vitamin A acid as taught by '146 also

increases the blood flow and increase the production of collagen and formation of new blood vessels (instant claims 6, 7, and 8).

Instant claims 6-8 are interpreted by the Examiner as functional limitations, which are characterization of the application method recited in instant claim 3. Accordingly, because prior art teaches, suggests and motivates the use of perfluorocompounds and Vitamin A acid as a emulsion used on the skin for treating abnormal regulation of skin capillary blood flow such application will result in increase synthesis of collagen and elastin fiber, increased flexibility of walls of precapillary arterioles and increase in reserve capillary blood flow (instant claims 6-8).

One would be motivated to make this combination of the said references to benefit from increasing the blood flow to the skin which results in younger looking skin, removes wrinkles and restores firmness and elasticity in the skin. Given the state of the art as evidenced by the teachings of the cited references and there would have been a reasonable expectation of success in combining the teachings of the cited references to obtain a topical emulsion to increase blood flow in the aging skin.

## ***Conclusion***

No claims are allowed. All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GEETA KADAMBI whose telephone number is (571)270-5234. The examiner can normally be reached on 8 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GEETA KADAMBI
Examiner
Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614